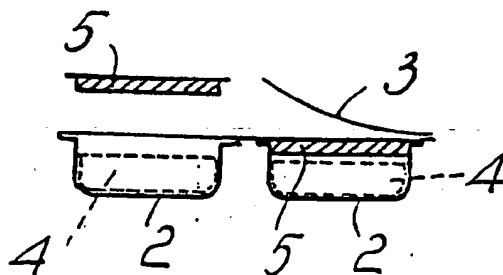




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/IT93/00010</p> <p>(22) International Filing Date: 11 February 1993 (11.02.93)</p> <p>(30) Priority data:  MI92A000306 13 February 1992 (13.02.92) IT  MI92A002037 31 August 1992 (31.08.92) IT</p> <p>(71) Applicant (for all designated States except US): TECNILENS S.R.L. [IT/IT]; Corso XXII Marzo, 34, I-20135 Milano (IT).</p> <p>(72) Inventor; and  (75) Inventor/Applicant (for US only): DI STEFANO, Stefano [IT/IT]; Piazza 5 Giornate, 7, I-20129 Milano (IT).</p> <p>(74) Agents: ADORNO, Silvano et al.; Societa' Italiana Brevetti, Via Carducci, 8, I-20123 Milano (IT) et al.</p>		<p>(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CZ, DE, DE (Utility model), DK, DK (Utility model), ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).</p> <p><b>Published</b>  <i>With international search report.  Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: MULTIPLE PACKAGE FOR PHARMACEUTICAL PRODUCTS



## (57) Abstract

A disposable packaging device, particularly for pharmaceutical products and the like and for the treatment of prostheses in general, includes at least one alveolus (2) suitable to contain a predetermined dose of pharmaceutical or treatment product (4) and seal closing means (5) of said alveolus suitable to separate said product from sealing means (3) of the alveolus. The latter are fixable on said support or externally contain it. In a preferred embodiment the packaging device includes a support (1) having a plurality of alveoli of pre-established size and a film (3) fixable on said support in a removable way, seal closing means (5) of each alveolus being provided, which separate said alveolus from said film.

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# Multiple package for pharmaceutical products.

The present invention concerns a disposable  
5 packaging device particularly suitable for  
pharmaceutical products and the like and for the  
treatment of prostheses in general.

It is known that confections called "blister" are  
often used for the packaging of medicines and the like  
10 of solid kind, said confections having a first sheet of  
plastic material in which alveoli are formed wherein  
medicines in solid preparation are inserted, and a  
second sheet, usually of composite type, which is fixed  
on the first sheet in order to protect the solid  
15 medicine preparations from polluting agents.

This technology, which has reached very high levels  
of specialization and competitive costs on the market,  
yet reveals itself nearly inadequate for preparations  
of medicinal type and the like, liquid or pulverulent.  
20 In particular, for the treatment, for example of  
maintenance or disinfection, of prosthesis members in  
general, such as removable dental members, contact  
lenses and the like, more or less complicated  
operations are presently necessary, requiring, as in  
25 the most frequent case of contact lenses, various  
containers for the lenses and the treatment solutions,  
as well as complicated pouring operations from a  
container to another.

The French patent application N.2.452.463 intends  
30 to solve the problem of the conservation and marketing  
of liquid physiological solutions for the treatment of  
contact lenses in blister-type containers as above  
mentioned. This patent application provides a plastic

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material support having a plurality of alveoli arranged in lines. A predetermined amount of liquid physiological solution for the treatment of contact lenses is contained within each alveolus. A film is  
5 fixed to said support, sealing the alveoli and retaining the liquid therein exclusively by means of the film.

This solution has major drawbacks in that it may happen that the film that is fixed to the support to  
10 seal the alveoli breaks up dispersing in the surrounding environment the liquid contained in the single alveoli, what may have even more serious consequences whenever it is the case of liquid or pulverulent medicinal preparations. The danger of  
15 breaking may take place especially when metallic films are used, in particular of aluminium, which may also have a certain degree of porosity which may cause, eventually, the evaporation of the product contained in the alveoli, or the penetration of polluting agents  
20 which may compromise its sterility and alter its chemical composition.

In order to avoid this, a multi-layer film has to be used, which is more expensive than a simple aluminium film. Anyway, once the sealing film has been  
25 removed, a dispersion of the preparation residues, if any, in the environment after the use is probable, which would be extremely serious especially in the case of vaccines or antibiotics ready to use inserted in such a confection.

30 Furthermore, two-components antibiotics are well known in pharmaceutical technology, that is medicines which, in one confection, have a phial containing a solvent and a small bottle containing an antibiotic in powder form, to be dissolved in the solvent prior to

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its administration. These confections result particularly bulky and expensive due to the need to use two containers different in shape and size, involving packaging problems which the above-mentioned French patent application can not solve.

Finally, for liquid medicinal preparations particularly sensitive to the polluting agents, the conventional type packagings presently used, though they perform excellently the tasks entrusted thereto, result particularly expensive. On the other hand, the solution suggested by the above-mentioned French patent application puts the preparation in contact with films which, though they are of the pharmaceutical and/or alimentary type, may always have on their surface polluting agents capable of altering the preparation inserted in each alveolus.

It is therefore an object of the present invention to eliminate or substantially reduce the above-mentioned drawbacks by providing a disposable packaging device, particularly for pharmaceutical products and the like and for the treatment of prostheses in general, which eliminates the risk of dispersion into the environment of the product contained in the alveoli, both in case of breaking of the covering film, and after the use, as far as the remained residues, if any, are concerned.

Another object of the present invention is to obtain a device which eliminates the risk of contamination of the product contained therein, due to the porosity or the breaking of the sealing film.

A further object of the present invention is to obtain a container which eliminates any risk of evaporation of the liquid contained therein.

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Yet another object of the present invention is to obtain a packaging device of high reliability, of easy production and use, with competitive costs and which provides the use, with the minimum waste, of an alveolus at a time for each treatment operation.

These and other objects are achieved by means of a disposable packaging device characterized in that it consists of a support comprising one or more alveoli provided with removable and reinsertable seal closing means suitable to separate said alveoli from the sealing means which contain the support or are fixed thereon.

Therefore, said device has the advantages of a double protection of the product against contamination and evaporation, and of an effective seal closing of the used alveoli, which prevents the dispersion of the product residues, if any, remained after the use.

Further characteristics and advantages of the disposable packaging device according to the present invention will be apparent from the description of some embodiments thereof, illustrated as non-limiting examples in the annexed drawings wherein:

Fig.1 is a top plan view of a packaging device according to the invention;

Fig.2 is a sectional view according to line II-II of fig.1;

Fig.3 is a view similar to that of fig.2 of a device with two alveoli, exemplifying how the seal closing and sealing means are used;

Fig.4 is a plan view similar to that of fig.1, with a plurality of a second type of alveoli;

Fig.5 is a sectional side view of a device with two alveoli of the second type illustrated in fig.4, and with different sealing means;

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Fig.6 is a plan view of a first seal closing means or plug;

Fig.7 is a plan view of an alveolus, in the embodiment of figs.4 and 5; and

5 Figs.8, 9 and 10 show sectional side views of some embodiments of alveolus with the respective seal closing and sealing means.

Referring to the drawings, in particular to figs.1-3, the packaging device according to the invention  
10 consists of a support 1 which comprises at least one alveolus 2 of pre-established size sealed in its upper part, for example by a film 3, and containing a predetermined dose of product 4, for example a treatment liquid for the disinfection and/or  
15 maintenance of prostheses such as contact lenses.

As a peculiar feature of the present invention, also seal closing means are provided, separating the product 4 contained in each alveolus 2 from the sealing means preferably consisting of a film which may be  
20 stuck or fixed on the support 1 and removed therefrom to use the product 4. Said seal closing means preferably consist, for each alveolus, of a plug 5 suitable to enter partially the mouth of the corresponding alveolus, extractable and reinsertable in  
25 the alveolus (see fig.3), preferably made of an alimentary/pharmaceutical type of material, having a certain elasticity.

Means for the irreversible dispensing of the liquid treatment product may also be provided, including a  
30 second pull-off plug (not shown) which seals an opening or small beak (not shown as well) formed in a peripheral wall of the alveolus. Said second plug, once it has been pulled off, allows the exit of the

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predetermined dose of liquid treatment product from said opening.

The alveoli 2 are preferably gathered in arranged groups, as shown in fig.1, according to the well known blister technology, in order to make their production easier and to reduce the costs thereof. The number and shape of the alveoli depend on the particular application for which the device is intended (for example according to the type of disinfection or maintenance treatment of prostheses). In particular, for the use in the field of the maintenance of contact lenses and/or the packaging of contact lenses reference will be made to the device illustrated in figs.4-7.

In a typical embodiment, shown in fig.5, the sealing means of the device consist of a sealed sachet 6 which externally includes a pair of alveoli 7 of a second type, each of them being provided with a respective sealing plug 8 but, differently from the alveoli 2 of figs.1-3, the alveoli 7 have an inclined portion 9 on their bottom which favours the extraction of a contact lens immersed in the physiological solution 10.

Moreover, where the edges of the sealing plug 8 come in touch with the mouth of the alveolus, small cavities 11 are provided to make easier the extraction of the plug. The latter may also be slightly sunken in its upper part in order to make possible the insertion between each plug and the sealing means of pills and/or powders of substances for particular treatments of each contact lens.

As far as the above considered application is concerned, relative to the contact lenses, such as the cleaning of the lens and other treatment baths, the



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advantages given by the packaging device according to the invention are apparent, said device:

- allowing the treatment of each single lens in a bath having an optimum dose of treatment liquid;
- 5        -permitting the treatment of a single lens too;
- allowing the use of the treatment liquid also in other types of container, thanks to the second pull-off plug which permits to pour the dose of liquid in other containers;
- 10       -assuring the sterility of the liquid, thanks to the seal and the plug 8, which prevent any contamination of the liquid prior to the opening of the alveolus;
- resulting easily disposable, in particular without
- 15       dispersing the liquid product 10 in the environment, thanks to the seal exerted by the plug 8 within the alveolus 7;
- eliminating all the risks, well known by contact lenses users, of residual dirt remained in the
- 20       container, typical in the case of reusable containers.

Obviously, these advantages are found also in the other possible applications of the device, in fact both the above-described embodiments are particularly useful for the packaging not only of solutions for the

25       treatment of contact lenses and the like, but also of fluid or semi-fluid preparations in general, such as single-dose syrups etc. which require the complete utilization of the alveolus contents.

In both the above-described cases, the support 1

30       has a plurality of weakness lines 12, or prearranged split lines, for the mutual separation of the alveoli. In this way it is possible to package in single alveoli also medicinal products which are different but necessary to the achievement of the preparation to be

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administered, such as the mentioned two-components antibiotics and other similar products, also non medicinal, but requiring an absolute isolation from the external environment due to contamination problems and the like.

On the other hand, whenever the packaging concerns medicinal preparations, such as antibiotics, vaccines and the like, in powder form and with the respective solvents, it is preferable to use other embodiments of the alveoli, described hereafter.

As shown in fig.8, an annular groove 13 constitutes the seat wherein the peripheral edge of the respective seal plug 14 is housed, said plug in turn being sealed, for example, by an overlying film 15, said groove 13 being formed near the mouth of the alveolus 16.

In fig.9, instead, two annular rims 17 and 18 are illustrated, defining an annular housing seat 19 wherein a respective seal plug 20 can be inserted, said plug being sealed, for example, by a film 21, said housing 19 being near the mouth of the alveolus 22, similarly to the preceding case.

A further embodiment, shown in fig.10, provides seal closing means of an alveolus 23 including also a plug 24 suitable to be housed in an annular groove 25 formed in a middle portion of the inner wall of the alveolus 23, in addition to a plug 26 insertable into the mouth of the alveolus in any of the above shown ways (for example, here reference has been made to the embodiment of fig.9).

While the plug 26, completely similar to the preceding seal closing plugs 14 and 20, separates the alveolus 23 from an external film 27, the inner plug 24 divides the volume of the alveolus 23 in two different areas, an upper one and a lower one, capable of

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containing different products. For example, a pharmaceutical product in powder form may be inserted in an area, and the respective solvent in the other one.

5       It should be noted that all the seal closing plugs are perforable, in particular those difficult to remove and indicated for medicinal products, that is those relative to the figs.8, 9 and 10. By means of injection needles and the like, the contents may be extracted  
10 from the respective alveoli, in case of liquid medicinal preparations, or it will be possible to inject solvent for medicines packaged in powder form and extract the medicinal mixture thus obtained in solution, in this latter case with particular reference  
15 to the embodiment of fig.10.

From the practical tests carried out it has been verified that the present invention is capable of achieving the appointed objects, being an efficacious alternative to the confections of known type, strongly  
20 reducing the use of expensive material, such as glass and the like, replaced by cheaper and easily recyclable materials, such as the plastic materials.

The packaging device according to the invention is obviously susceptible of several changes and versions  
25 compared to the above-described and illustrated embodiments, always remaining within the purview of the invention. For example, the sealing plugs may be fixed within the respective alveoli by fixing rings or other similar devices, and all the elements may be replaced  
30 by other mechanically equivalent elements, while the materials used as well as the shape, number and size of the alveoli may be any, according to the requirements.

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## CLAIMS

1. A disposable packaging device, particularly for pharmaceutical products and the like and for the treatment of prostheses in general, characterized in that it consists of a support (1) including at least one alveolus (2, 7, 16, 22, 23) and of removable and reinsertable seal closing means of said alveolus, suitable to separate said alveolus from sealing means of said alveolus external to said support (1) or fixable thereon.

2. A device according to claim 1, characterized in that said support (1) includes a plurality of alveoli (2, 7, 16, 22, 23) arranged in lines.

3. A device according to claim 1, characterized in that the seal closing means are perforable by means of an injection needle or the like.

4. A device according to claim 3, characterized in that the seal closing means include a plug (5, 8, 14, 20, 26) of a material of the alimentary/pharmaceutical type having characteristics of elasticity.

5. A device according to claim 3, characterized in that the sealing means include a film (3, 15, 21, 27) suitable to stick to said support (1) and to be removed therefrom or to be perforated to use the product, upon removal or perforation of the underlying seal closing means.

6. A device according to claim 4, characterized in that each alveolus (16, 22) has an annular seat (13, 19), in the peripheral wall near the mouth, suitable to house the peripheral edge of the seal closing plug (14, 20, 26).

7. A device according to claim 6, characterized in that the annular seat (19) is formed by two annular rims (17, 18).

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8. A device according to claim 6 or 7, characterized in that, in addition to the annular seat (13, 19), each alveolus (23) has a second annular seat (25) in the middle area in height of the peripheral wall, suitable to house a second sealing plug (24) suitable to separate the inner volume of the alveolus (23) into two different areas one on top of the other.

9. A device according to claim 1, characterized in that the alveolus (7) has an inclined bottom area (9).

10 10. A device according to claim 4, characterized in that the support (1) is provided with cavities (11) positioned by the edge of the plug (5, 8) and suitable to favour the removal of said plug (5, 8).

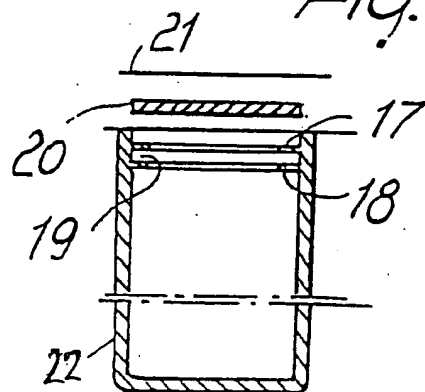
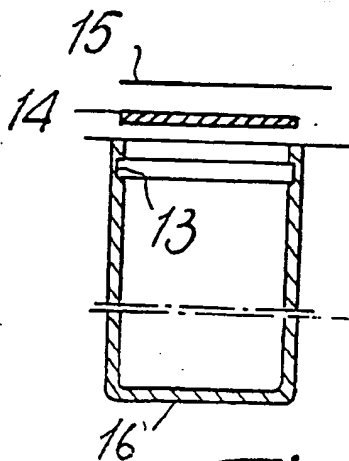
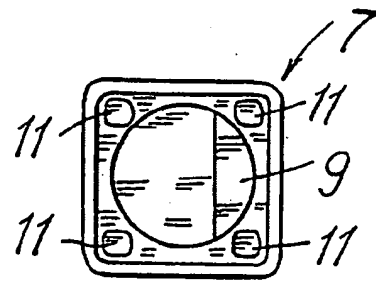
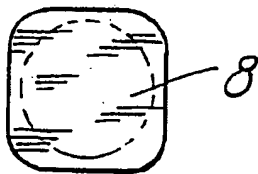
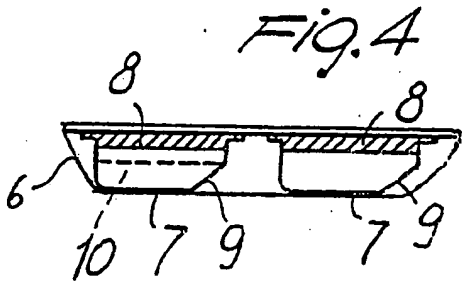
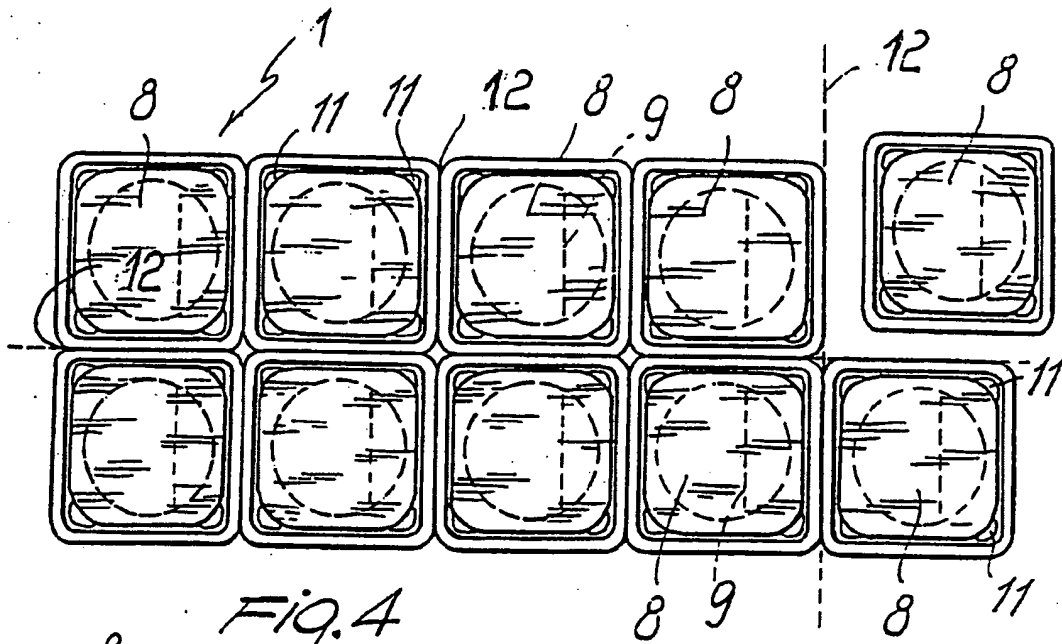
15 11. A device according to claim 2, characterized in that the support (1) has a plurality of prearranged split lines (12) suitable to allow the separation of the single alveoli (2, 7, 16, 22, 23).

20 12. A device according to claim 2, characterized in that said device includes also a predetermined dose of pharmaceutical product or of product for the treatment of prostheses in general (4, 10) contained in each alveolus (2, 7, 16, 22, 23).

25 13. A device according to claim 12, characterized in that the support (1) includes a pair of alveoli (2, 7, 16, 22, 23) and is externally contained by a sealed sachet (6).

30 14. A device according to one or more of the preceding claims, characterized in that the alveolus (2, 7, 16, 22, 23) is provided also with a non-reclosable plug which closes an opening or a small beak located in the lower part of said alveolus and suitable to allow the exit of the whole contents of said alveolus.





## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IT 93/00010

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 B65D75/34; B65D51/00		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
Int.Cl. 5	B65D	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	FR,A,982 538 (NICOLLE) 12 June 1951 see the whole document	1,2,5-8, 12 3,9,13 10
Y		
A		
X	US,A,3 343 897 (KELLER) --- 26 September 1967 see column 3, line 35 - column 4, line 21; figures 9-16	1,8,11, 12
Y	DE,A,2 303 684 (TABAK) --- 5 September 1974 see page 8, line 22 - page 9, line 13; figure 5	3
A	US,A,4 499 148 (GOODALE) --- 12 February 1985 see abstract; figures see column 1, line 18 - column 1, line 26 --- -/--	4
<p><sup>10</sup> Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
01 JUNE 1993		18.06.93
International Searching Authority		Signature of Authorized Officer
EUROPEAN PATENT OFFICE		NEWELL P.G.



III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	EP,A,0 084 119 (PLASTIK FUR DIE MEDIZIN) 27 July 1983 see page 7, line 28 - page 8, line 22; figures 1-4 ---	9
Y	US,A,3 331 495 (LECKZIK) 18 July 1967 see column 1, line 55 - column 2, line 11; figures ---	13
A	US,A,3 650 390 (HOON) 21 March 1972 see abstract; figures 1-6,12 -----	14

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

IT 9300010  
SA 70733

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.  
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01/06/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-982538		None	
US-A-3343897		None	
DE-A-2303684	05-09-74	None	
US-A-4499148	12-02-85	None	
EP-A-0084119	27-07-83	DE-A- 3201244	28-07-83
US-A-3331495		None	
US-A-3650390	21-03-72	None	